ANTISPETIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash
Chain Drug Manufacturing Assn

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts Quality Choice 072.003/072AN

Active ingredients

Eucalyptol 0.092%

Menthol 0.042%

Methyl salicylate 0.060%

Thymol 0.064%

Purpose

Antigingivitis, antiplaque

Use

help control plaque that leads to gingivitis

Warnings

Warnings for this product

Do not use

if you have painful or swollen gums, pus from the gum line, loose teeth or increased spacing between the teeth. See your dentist immediately. These may be signs of periodontitis, a serious form of gum disease.

Stop use and ask a dentist if

gingivitis, bleeding, or redness persists for more than 2 weeks.

Keep out of reach of children.

If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years of age and older - vigorously swish 20 mL (2/3 FL OZ or 4 teaspoonfuls) between teeth for 30 seconds then spit out; do not swallow

children under 12 years of age - consult a dentist or doctor

- this rinse is not intended to replace brushing or flossing

other information

cold weather may cloud this product. Its antiseptic properties are not affected. Store at room temperature (59º - 77º F)

Inactive ingredients

water, alcohol 21.6%, sorbitol solution, flavoring, poloxamer 407, benzoic acid, sodium saccharin, sodium citrate, D&C yellow no. 10, FD&C green no.3

Disclaimer

This product is not manufatured or distriubted by Johnson & Johnson Healthcare Products, distributor of FreshBurst Listerine Antiseptic Mouthwash.

Adverse Reactions

Distributed by C.D.M.A., Inc

43157 W 9 Mile Rd

Novi, MI 48375

www.qualitychoice.com

Questions: 800-93-2362

principal display panel

QC

QUALITY

CHOICE

Compare to FreshBurst

LISTERINE

Antiseptic Mouth Rinse

Antigingivitis/Antilaqu

Kills Germs That Cause:

Bad Breath

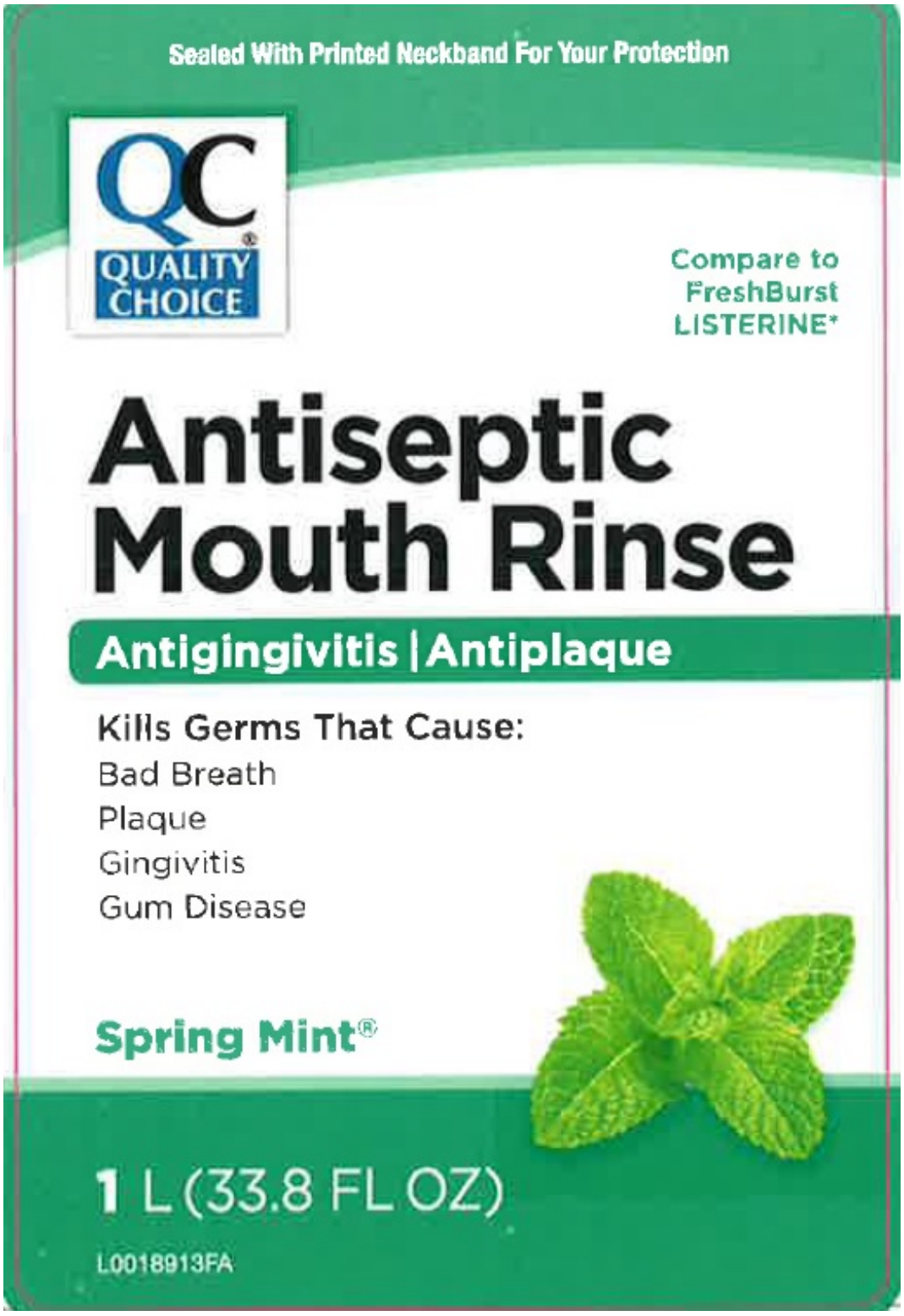
Plaque

Gingivitis

Gum Disease

Spring Mint

1 L (33.8 FL OZ)



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eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-214
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)	EUCALYPTOL	0.92 mg in 1 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.42 mg in 1 mL
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.60 mg in 1 mL
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	0.64 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
SORBITOL (UNII: 506T60A25R)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-214-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/28/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	12/28/2010	

Labeler - Chain Drug Manufacturing Assn (011920774)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(63868-214)